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(71)(72) Applicant and Inventor: CHANDLER, Jerry, W. [US/US]; 2631 Lanark Road, Birmingham, AL 35223 (US).

(74) Agent: FREEMAN, John, C.; Willian, Brinks, Olds, Hofer, Gilson & Lione, NBC Tower, Suite 3600, 455 North Cityfront Plaza Drive, Chicago, IL 60611 (US).

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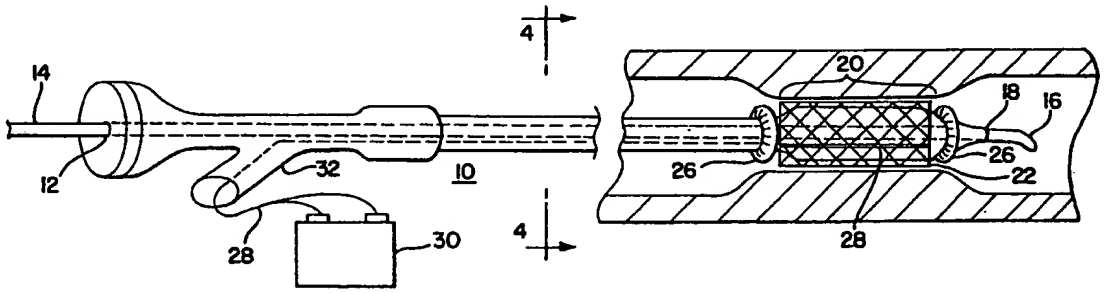

(57) Abstract

A stent (24) made of a biodegradable copolymer is applied to the exterior surface of an angioplasty balloon (22). Upon being positioned at a restricted vessel section (20) a contrast fluid present in the balloon (22) is heated which results in the stent (24) being heated. Heating the stent (24) and expanding the angioplasty balloon (22) allows the stent (24) to expand so that it presses against the vessel wall. The balloon (22) is then collapsed leaving the stent (24) in position.

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BIODEGRADABLE STENT

BACKGROUND OF THE INVENTION

The present invention generally relates to the implantation of structures in a blood vessel to maintain the blood vessel's patency. Specifically it relates to the use of a stent to maintain blood vessel patency following procedure such as angioplasty or atherectomy.

Obstructive coronary artery disease is one of the most serious health problems facing our society today. This disease is the result of the deposit of fatty substances on the interior surface of the walls of the arteries. The build-up or lesion of such deposits results in a narrowing of the diameter of the artery which restricts the blood flow through the artery. This condition wherein the artery is narrowed is known as stenosis. The lesion may form in any part of the artery. In some instances the deposits may form at the intersection between two arteries, that is, the section where the two arteries form a generally "Y" configuration (e.g. bifurcate, trifurcate, and so on).

There have been significant developments in the treatment of such obstructive coronary disease in the recent past. One such treatment is coronary artery bypass graft surgery. In bypass surgery, a healthy graft of a blood vessel is taken from the patient's body (usually a vessel from the leg) and used to bypass the diseased portion of the coronary vessel. Bypass surgery, however, is extremely invasive and traumatic to the patient.

Some of the recent developments provide a less invasive and less traumatic alternative to bypass sur-

gery. Two of these recent developments are known as balloon angioplasty and atherectomy procedures.

Balloon angioplasty is used to open arteries in which the blood flow has been significantly reduced by the build-up of arteriosclerotic plaques on the interior of the artery walls. The angioplasty technique consists of inserting into the blood vessel a catheter with a small balloon attached at its distal end. The catheter is moved along the vessel until it reaches an area where the blood flow is impeded by plaque build-up. The balloon portion is then inflated forcing or compressing the plaque against the vessel wall. The balloon is then deflated and removed. Since the plaque is compressed, the cross-sectioned area of the vessel is increased and the treated vessel area experiences improved blood flow. An example of a balloon angioplasty device is described in "New Passive Perfusion PTCA Catheter" by White et al. The article describes a dual chamber balloon catheter. Another dual chamber balloon catheter is described in U.S. Patent No. 5,047,045 issued to Arney et al.

Atherectomy is a procedure in which a small cutting or grinding tool is attached to the end of a small diameter flexible catheter and maneuvered through the patient's arterial system to the site of the lesion in the diseased artery. When the cutting tool is properly positioned, the tool is used to cut and remove the deposits from the surface of the diseased artery.

Although these two procedures provide less traumatic alternatives to bypass surgery, they are not without complication. It is possible that following procedures such as angioplasty or atherectomy, the artery or blood vessel may collapse or be susceptible to constriction. In some instances it may also be necessary to use "bail-out" procedures such as repeat angioplasty, atherectomy, or placement of a permanent stent, due to some type of unexpected complication.

For the most part, complications from the angioplasty procedure occur several months after the procedure has been completed. At that time approximately one third of the treated arteries undergo chronic restenosis, a reclosing of the artery at the treated area. In addition, a condition known as acute arterial occlusion may result. Acute arterial occlusion is usually caused by an obstructive dissection of the arterial intima or inner lining. Following balloon angioplasty, the intima may be disrupted and may collapse into the lumen of the artery causing impeded blood flow. If the impedance is severe enough, the patient may be required to undergo emergency coronary artery bypass graft surgery to prevent a heart attack. Further, the occurrence of restenosis may require another angioplasty procedure. In order to avoid multiple angioplasty treatments performed at the same vessel area, techniques have been contemplated to prevent future restenosis from occurring at the treated vessel section.

The most promising technique to date to prevent restenosis is the implantation of "stents" in the blood vessel at the position in the blood vessel where the balloon was inflated. A stent is a short tube, open at both ends, which presses firmly against the vessel wall to prevent restenosis from occurring. The stents are preferably implanted immediately after the balloon angioplasty is completed and the balloon is removed.

In addition to preventing restenosis in arterial vessels, stents may be used in the treatment of aorto-coronary saphenous vein graft stenosis.

One of the earlier stents was constructed of stainless steel coil springs implanted in the vessel. C. T. Dotter in the September-October 1969 publication of Investigative Radiology reported the successful use of a bare stainless steel coil as a stent. When the coil was implanted, a layer of endothelium material naturally spread over the coil structure to form a tubular element.

This tubular element had the structural strength to prevent the vessel from occluding.

With Dotter's disclosure came many improvements in the placement and structure of stents. One improvement was in having the stent conform more exactly to the shape of the vessel area. In particular, U.S. Patent No. 4,503,569 by Dotter discloses a "shape memory" stent. The stent disclosed in this patent is made of nitinol, an alloy of titanium and nickel. The alloy is formed into a helical shape and is heated to a size which conforms to the size of the vessel. Once heated the nitinol memorizes the desired shape. Next the coil is wound tighter so as to allow for the coil to be easily placed at the vessel area by a catheter. Once at the vessel area the coil is heated by passing warm (115-125°F) saline solution through a catheter. The coil expands to its memorized size and the coil firmly presses against the vessel wall.

Another example of a stent is the so-called Palmaz-Schatz stent described in the following articles: (1) "Expandable Intraluminal Vascular Graft: A Feasibility Study;" (2) "Normal and Stenotic Renal Arteries: Experimental Balloon-expandable Intraluminal Stenting;" (3) "Balloon-expandable Intracoronary Stents In The Adult Dog;"(4) "Atherosclerotic Rabbit Aortas: Expandable Intraluminal Grafting;" and (5) U.S. Patents Nos. 4,739,726 and 4,776,337. In these articles and patents a balloon expandable stent is disclosed which relies on plastic deformation of metal beyond its elastic limit. Consequently, once the metal is stretched beyond a certain limit, it cannot collapse.

The balloon expandable stent is first placed over a balloon of a balloon angioplasty device. The balloon and stent are then positioned at a vessel section experiencing stenosis. The balloon is expanded by filling it with either a fluid or gas. The balloon is expanded until the stent presses against the vessel wall. The balloon is then deflated whereupon the stent remains

pressed against the vessel wall, because it has been expanded beyond its elastic limit. One problem with metallic expandable stents is that their insertion may result in arterial wall compliance mismatch which may lead to intimal hyperplasia. Another method of insertion is disclosed in WO 90/01969 by Slepian et al. where a current running through a wire may be used to heat the stent so as to expand it to a size such that it is attached to the vessel wall.

With the increasing interest in the use of stents it is apparent that an ideal stent should have several properties. First, an ideal stent should be non-thrombogenic to both fibrin and platelets. Metal stents are inherently thrombogenic and attract platelets. Being thrombogenic, the use of such metal stents necessitates the use of drug therapies that may be required for an extensive time period until new endothelial cells have formed. One possible solution being employed is the coating of the metal stents with a polymer or by coating the metal with heparin. Furthermore, the polymer coating may contain a drug to be released in the blood stream. The release of drugs from a stent are disclosed, for example, in WO 90/01969 by Slepian et al., EP 0292587 by Strecker, the article "Bioabsorbable Endovascular Stent Protheses" and the article "Intracoronary Stenting: Bailout or Bypass?" by Murphy et al. U.S. Patent No. 4,713,402 also discloses a copolymer material with anti-thrombogenic and/or antimitotic drugs. U.S. Patent No. 4,702,917 discloses a polymer structure having an inner reservoir containing a drug to be released through a copolymer structure encompassing the reservoir wherein the copolymer may consist of a caprolactone and another lactone.

Second, the ideal stent should be biodegradable since it then would be located in the vessel for a limited period of time. Though the metals used for stents are relatively inert the long term presence of a metal in the

vessel may lead to complications as of yet unknown. Also, the use of polymers to coat the metallic stent may not be without disadvantages. For example, the polymer PET (polyethylene pterephthalate) may lead to a negative reaction by the patient. Biodegradable materials consisting of copolymers of D,L-Lactide and epsilon caprolactone are well known to be used in manufacturing gummy adhesives and self-supporting rigid objects for automobiles, housing, appliances, household goods, and packaging as disclosed in U.S. Patents Nos. 4,045,418 and 4,057,537.

It is well known to use biodegradable ureteral stents in EP 420 541 and Canadian Patent No. 2,025,626 each by Goldberg et al. Such stents consist of a terpolymer of L(-)lactide, epsilon-caprolactone, and glycolide. It also discloses a copolymer of 85% L(-)lactide and 15% epsilon-caprolactone tested as a ureteral stent. However, the 85/15 copolymer does not possess adequate hoop strength to be used for a stent with a mesh structure and/or thin walls used to prevent restenosis in a blood vessel.

In 1990, a bioabsorbable mesh stent was disclosed by Dr. Richard Stack in an abstract presented to the American Heart Association. The stent material used was self-expandable and composed of 100% L-Lactide. Self expanding stents of any kind however, have significant limitations. For example, if the stent is sized too large, it will stretch the artery and possibly damage the artery or cause intimal dissection. If the stent is undersized it may migrate in the vessel. Furthermore, EP 420 541 discloses a biodegradable stent comprising a terpolymer of L-lactide, glycolide, and epsilon-caprolactone and the article "Bioabsorbable Endovascular Stent Prostheses" by Gammon et al. discloses a stent comprising a poly-L-lactide.

An ideal stent must be easily delivered to the point of interest to prevent long delays in the proce-

dure. Metal stents are difficult to deliver, especially in distal lesions and in tortuous vessels, since they lack the maximum collapsibility and flexibility required. An ideal stent must be sufficiently flexible to be expanded to engage the vessel wall.

Finally an ideal stent must have sufficient "hoop strength" to prevent elastic arterial wall recoil and to allow intimal dissections to be "tacked-up" or supported.

Therefore, it is a primary objective of the present invention to provide a stent which is easily implantable, nonthrombogenic, bioabsorbable, which can be sized with a high degree of accuracy and has sufficient properties of flexibility and hoop strength to provide a viable stent.

SUMMARY OF THE INVENTION

To achieve this objective, the present invention comprises a stent formed of a co-polymer material which has the properties of being biodegradable, biocompatible, flexible, strong to ensure vessel patency. The co-polymer is advantageously biodegradable such that it is capable to only remain in the vessel as long as it is needed. Once the stent is no longer needed the stent would degrade. The co-polymer composition has material properties that allow it to be flexible at one stage of its placement and then to become strong at a later placement stage. These properties ensure ease in delivery of the stent and ensure the nonoccurrence of restenosis.

Following traditional angioplasty, a novel method of inserting the stent is performed. First, the stent material is placed on the outside of an angioplasty balloon. Next, the balloon is inflated to press the stent material against the vessel wall while the stent is heated through the balloon catheter. After the stent has cooled down, the balloon is deflated. The stent material is released from the balloon and attaches to the vessel

wall after being expanded. The hoop strength of the stent on the vessel wall is of sufficient strength to prevent acute restenosis from occurring.

In a preferred embodiment, the stent material may carry a time-released drug. Upon degradation, a drug carried by the stent can be released to the surrounding vessel wall to control processes such as mitosis, coagulation, and fibrinolysis.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a preferred embodiment of the present invention in an uninflated stage positioned at a vessel section where the blood flow is impeded;

FIG. 2 illustrates the embodiment of FIG. 1 in an inflated stage with the balloon catheter still present;

FIG. 3 illustrates the embodiment of FIG. 1 with the balloon catheter deflated and removed from the vessel; and

FIG. 4 is a cross-section of the preferred embodiment of the balloon angioplasty device used to perform the stent implantation.

DETAILED DESCRIPTION OF PRESENTLY PREFERRED EMBODIMENTS OF THE INVENTION

The present invention will now be described in more detail with reference to the Figures. Fig. 1 illustrates the basic structure of a preferred embodiment of the device used to implant the stent. In Fig. 1, a modified angioplasty catheter 10 having a length of about 135 cm and a diameter of about 1.5 mm is used. At one end is an opening 12 which receives a guide wire 14. As is well known, the guide wire is directed through the angioplasty device 10 until its distal end 16 projects through a distal opening 18 of the angioplasty device 10. The distal end 16 of the guide wire is then used to direct the angioplasty device to a constricted blood vessel section 20, such as an arterial lesion.

The angioplasty device 10 also comprises a balloon 22 made of a suitable material such as polyethylene and having a length of about 2 cm. The balloon 22 has placed on its exterior a stent 24 comprising a copolymer material and having a mesh design. The stent here is in a first unexpanded state. On either side of the balloon 22 and stent 24 are plastic ferrules 26 which prevent the stent 24 from moving off of the balloon 22. The preferred size of the ferrules 26 is 2 mm, although a range of from about 1.5 cm to about 2.5 cm may be suitable.

The polymer stent preferably comprises two polymers comprising a lactide and a caprolactone, namely: poly (L-lactide) (L-PLA) and poly (ϵ-caprolactone) (CPL). In a working example, the L-lactide (L-PLA) constitutes approximately 90-99% and caprolactone approximately 1-10% of the stent material. Preferably, the L-lactide (L-PLA) constitutes approximately 95% and caprolactone approximately 5% of the stent material. In another working embodiment DL-lactide (DL-PLA) may be substituted for L-lactide in the copolymer described above. The choice of L- and DL-lactide with epsilon caprolactone is the result of combining the desirable hoop strength properties of L- and DL-lactide and the desired flexibility properties of epsilon caprolactone. Thus, the copolymer is able to be used as a stent with a mesh structure and/or thin wall to prevent restenosis in a blood vessel.

Monofilaments of both bioresorbable polymers for the stent may be fabricated by a conventional melt extrusion process using a piston and a spinneret. The process is performed at a temperature of approximately 175-200° C for the 95/5% polymer combination and at 100°C for the DL-PLA polymer. A force of approximately 110 pounds is placed on the piston which causes the extrusion of the DL-PLA polymer through the spinneret. A force of about 165-200 pounds is placed on the piston for the 95/5% L-PLA polymer combination. The spinneret size can

be adjusted to the desired diameter. The resulting monofilament fibers have a diameter of about 0.1-0.30 mm. The length of the fibers is determined by the size of the area of interest, the stent, and the mesh configuration. The fibers formed may be then tensile tested at ambient temperature. The fibers may then heat set by passing them through a heated tube having a length of about 3-4 feet and diameter of about 0.5-1.0 inches. A suitable temperature for the heated tube is 45°C at ambient pressure.

The heat setting step imparts some degree of permanence and dimensional stability to the fiber. Finally, the fibers may be subjected to a headsetting step after deployment to make them pliable during balloon expansion. The heatsetting step involves heating a liquid to ambient temperature and then heating the liquid by a wire to 45°C as described later in the specification.

This material is woven into a mesh of monofilaments that range in diameter from approximately 0.1 mm to 0.3 mm. On the deflated balloon, the stent is tightly wound around the angioplasty balloon, and the monofilaments are about 0.1-2.0 mm apart depending on the diameter of the balloon used, the percent composition of the stent material, and the size of the vessel to be dilated. For example, the more epsilon caprolactone used the stent material becomes weaker but more flexible and the more L- and DL-lactide used the stent material becomes less flexible. Consequently, to compensate for the effect of adding more epsilon caprolactone the stent is strengthened by winding the monofilaments closer together and provide less air space between them.

The mesh configuration is woven using a conventional textile process. The stent may also have other configurations such as a spiral. To place the stent on the balloon 22, the stent is heated until the transition temperature is reached and then the stent is cooled. Once cooled the stent material is then attached to the

balloon's exterior surface by winding it tightly around the deflated balloon. In this state, the stent retains its wound shape because the fiber is relatively rigid. In its wound shape the stent has an inside diameter ranging from approximately 0.025" to 0.080" and an outside diameter ranging from approximately 0.034" to 0.100" depending on the size of the deflated balloon to be used for a particular blood vessel. The fiber cannot move forward or backward due to the ferrules 26. The fibers elongate only when heated and stretched by the expanding balloon during balloon inflation with a heated liquid medium. When the stent is heated by the electric wire, the stent will expand to the same size as the expanded balloon. The size of the balloon can be controlled by the liquid medium injected into the balloon under pressure. Preferably, the balloon has a cylindrical-like shape when expanded with a range of lengths from approximately 2 cm to 4 cm and a range of diameters from approximately 0.25 cm to 0.80 cm depending on the size of the vessel to be dilated.

In addition to the guide wire 14, the angioplasty device 10 contains an electric wire 28. A suitable wire is formed of a conducting material such as copper and preferably having a length of approximately 200 cm and a diameter ranging from about 0.006 to 0.010 cm. The electric wire 28 is connected at one end to an electrical power device 30, such as a battery. The voltage of the power device 30 is preferably in a range from approximately 4.5 volts to 10 volts so to produce a current ranging from approximately 1.0 to 2.0 amperes. The electrical wire 28 is inserted into the angioplasty device 10 at a side opening 32. The wire is directed parallel to the guide wire and its distal end is present in the balloon 22. The electrical wire is insulated from the electrical power source 30 to just before entering the balloon 22. That part of the electrical wire 28

present in the balloon 22 is not insulated so that it can act as a heating element in the balloon 22.

Once the angioplasty device is positioned at the restricted region 20 as illustrated in Fig. 1, the balloon 22 and stent 24 are expanded to a second state so as to press closely against the vessel wall thus opening up the restricted area in the process. Expansion is achieved by first injecting a contrast material into the balloon to inflate the balloon and then running a current through the electrical wire 28 to heat the contrast material. The use of contrast material enables the physician to track and position the balloon. A preferred contrast material is available under the tradename of Hypaque and the material may be mixed with a saline solution to produce a 50% contrast/50% saline injection material. The current then heats up the liquid injection material to a temperature of 45°C which in turn heats up the polymer stent making it more pliable.

Other alternatives for heating the stent include embedding a fine wire in the balloon material, ultrasound, or laser heating. Furthermore, the contrast medium may be heated inside the balloon by a continuous system available from the Mansfield Company. The continuous system has the contrast medium injected under pressure through the catheter, into the balloon, and out of the balloon through a separate port which comes back into the proximal end of the catheter and is bled out of the balloon. Thus, a continuous column of heated contrast material is formed.

As discussed, the stent is heated by warm contrast medium injected into the balloon. The co-polymer is more pliable during heating allowing expansion of the stent. After cooling of the stent by convection to body temperature, the stent once again becomes more rigid and remains permanently in this second expanded state allowing adequate hoop strength to maintain the patency of the vascular structure as shown in FIG. 2.

Once the stent is expanded against the vessel wall, the balloon collapses leaving the stent pressing against the vessel wall. The angioplasty device is then removed from the formerly restricted vessel area as shown in Fig. 3. Once in place the stent prevents acute restenosis from occurring.

In another preferred embodiment, pharmacologic agents may be incorporated in the stent through microencapsulation and/or adsorption. Possible drugs contemplated are anti-mitotic agents, anti-coagulants, anti-growth factors, fibrinolytic agents, anti-platelet agents, anti-oxidant agents, lipid lowering agents, and/or steroids.

If, during deployment into the vascular structure, the stent is found to be easily dislodged from the balloon over the ferrules 26, a thin plastic sheath may be placed over the entire catheter device, including the balloon and stent. The sheath acts as a protective barrier that would hold the stent in place. Once the stent and balloon have been placed across the previously dilated arterial lesion, the sheath is withdrawn proximally, thus exposing the stent and balloon. The stent can then be heated and expanded as previously described. A similar device is presently in use with self-expanding metal stents.

The angioplasty device used in Figs. 1-3 is similar to those used in standard balloon catheter systems except it employs a larger lumen to house the guide wire. The guide wire lumen enables one to infuse oxygenated blood through it while the balloon is inflated and the wire is removed. This allows for longer inflations since the artery is occluded during balloon inflations. As shown in the cross-sectional view of the catheter of Fig. 4, the catheter has a second lumen 36 which is larger in size than lumen 34. Lumen 36 is preferably a half-cylindrical in shape. Second lumen 36 is not coaxial

with the first lumen 34 so that each enclose separate areas of the catheter.

Lumen 36 contains the insulated electrical wire 28 and is connected to the balloon 22. Lumen 34 contains guide wire 14 and is used to transport contrast material from outside the body to the balloon 22.

While the invention has been described with relation to certain presently preferred embodiments, those with skill in this art will recognize other modifications of the invention which will still fall within the scope of the invention, as expressed in the accompanying claims. For example the described stent device and implantation process may be used to ensure patency of other anatomical vessels such as urinary, reproductive, venous, or respiratory tubular structures.

I CLAIM:

1. A stent having sufficient hoop strength and flexibility to prevent occlusion of an area of a blood vessel comprising:

a tube in the shape of a mesh and having a first end and a second end where the distance between the first and second ends is sufficient to overlap said area of said blood vessel;

the tube comprising a lactide and a caprolactone and having a first unexpanded state and expandable to a second state upon heating and then cooling the tube while in the second state.

2. The stent of Claim 1, wherein the lactide comprises L-lactide.

3. The stent of Claim 1, wherein the lactide comprises DL-lactide.

4. The stent of Claim 2, wherein the stent comprises approximately 90-99% L-lactide and 1-10% caprolactone.

5. The stent of Claim 4, wherein the stent comprises approximately 95% L-lactide and 5% caprolactone.

6. The stent of Claim 1, wherein said caprolactone comprises epsilon caprolactone.

7. The stent of Claim 2, wherein said caprolactone comprises epsilon caprolactone.

8. The stent of Claim 4, wherein said caprolactone comprises epsilon caprolactone.

9. The stent of Claim 5, wherein said caprolactone comprises epsilon caprolactone.

10. The stent of Claim 3, wherein the stent comprises approximately 90-99% DL-lactide and 1-10% caprolactone.

11. The stent of Claim 10, wherein the stent comprises approximately 95% DL-lactide and 5% caprolactone.

12. The stent of Claim 3, wherein said caprolactone comprises epsilon caprolactone.

13. The stent of Claim 10, wherein said caprolactone comprises epsilon caprolactone.

14. The stent of Claim 11, wherein said caprolactone comprises epsilon caprolactone.

15. A stent delivery catheter employing a stent having sufficient hoop strength and flexibility to prevent occlusion of an area of a blood vessel comprising:

a catheter tube;

an inflatable balloon disposed on the distal end of the catheter tube;

the catheter tube having an inflation lumen for providing inflation pressure to the balloon to expand the balloon to predetermined size;

a heating element for heating the balloon; and

a stent comprising a tube having a first end and a second end where the distance between said first and second ends is sufficient to overlap said area of said blood vessel, the tube having a mesh shape and comprising a co-polymer of a lactide and a caprolactone and having a first unexpanded state and expandable to a second state upon heating and then cooling the tube while in the second state.

16. The stent delivery catheter of claim 15, wherein said electrical wire is situated inside said lumen.

17. The stent delivery catheter of claim 15, wherein the heating element comprises an electrical wire connected to a power source.

18. The stent delivery catheter of claim 15, further comprising a guide wire.

19. The stent of Claim 15, wherein the lactide comprises L-lactide.

20. The stent of Claim 15, wherein the lactide comprises DL-lactide.

21. The stent of Claim 19, wherein the stent comprises approximately 90-99% L-lactide and 1-10% caprolactone.

22. The stent of Claim 21, wherein the stent comprises approximately 95% L-lactide and 5% caprolactone.

23. The stent of Claim 15, wherein said caprolactone comprises epsilon caprolactone.

24. The stent of Claim 19, wherein said caprolactone comprises epsilon caprolactone.

25. The stent of Claim 21, wherein said caprolactone comprises epsilon caprolactone.

26. The stent of Claim 22, wherein said caprolactone comprises epsilon caprolactone.

27. The stent of Claim 20, wherein the stent comprises approximately 90-99% DL-lactide and 1-10% caprolactone.

28. The stent of Claim 27, wherein the stent comprises approximately 95% DL-lactide and 5% caprolactone.

29. The stent of Claim 20, wherein said caprolactone comprises epsilon caprolactone.

30. The stent of Claim 27, wherein said caprolactone comprises epsilon caprolactone.

31. The stent of Claim 28, wherein said caprolactone comprises epsilon caprolactone.

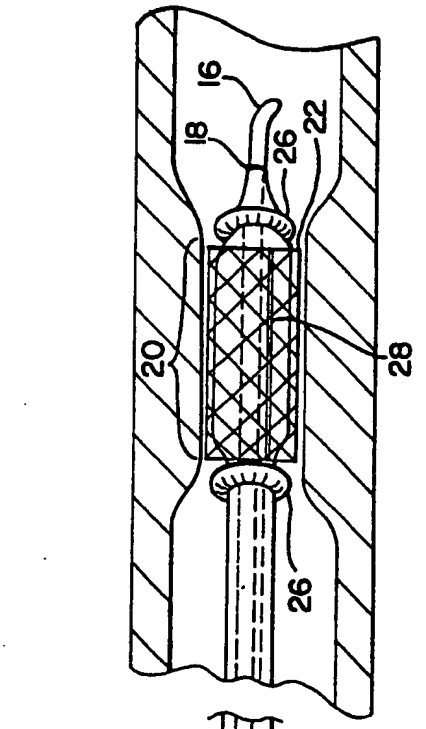


FIG. 2

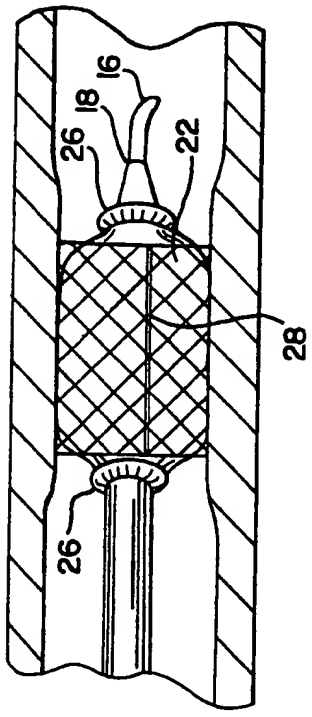


FIG. 3

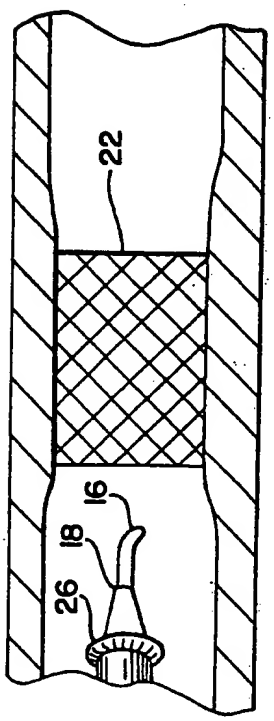


FIG. 1

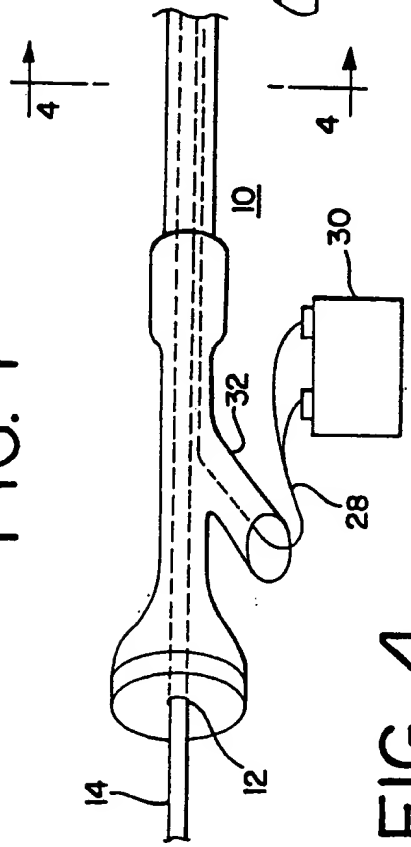
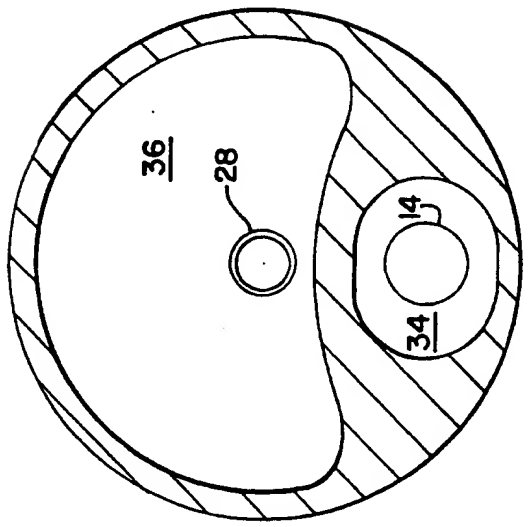


FIG. 4



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International application No.
PCT/US93/01297

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 29/00
US CL :
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1,,12,13,66; 606/27,28,191,194,195,200; 604/96-101; 128/899

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US,A, 5,085,629 (Goldberg et al.) 04 February 1992 See entire document.	1,2,6,7 3,12
Y	US,A, 4,938,763 (Dunn et al.) 03 July 1990 See entire document.	3,12

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date		
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed	"&"	document member of the same patent family

Date of the actual completion of the international search 28 MAY 1993	Date of mailing of the international search report 18 JUN 1993
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer WILLIAM LEWIS Telephone No. (703) 308-0858

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